

§ 184.1698

21 CFR Ch. I (4–1–04 Edition)

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in milk products, as defined in §170.3(n)(31) of this chapter, at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51148, Nov. 7, 1983]

§ 184.1698 Rue.

(a) Rue is the perennial herb of several species of *Ruta* (*Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.). The leaves, buds, and stems from the top of the plant are gathered, dried, and then crushed in preparation for use, or left whole.

(b) The ingredient is used in all categories of food in accordance with §184.1(b)(2) of this chapter at concentrations not to exceed 2 parts per million.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 3705, Jan. 27, 1978]

§ 184.1699 Oil of rue.

(a) Oil of rue is the natural substance obtained by steam distillation of the fresh blossoming plants of rue, the perennial herb of several species of *Ruta*—*Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.

(b) Oil of rue meets the specifications of the "Food Chemicals Codex," 4th ed. (1996), pp. 342–343, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Parts per million	Function
Baked goods and baking mixes, §170.3(n)(1), of this chapter.	10	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter.
Frozen dairy desserts and mixes, §170.3 (n)(20) of this chapter.	10	Do.
Soft candy, §170.3(n)(38) of this chapter	10	Do.
All other food categories	4	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 64 FR 1760, Jan. 12, 1999]

§ 184.1702 Sheanut oil.

(a) Sheanut oil is produced from sheanuts derived from the Shea tree *Butyrospermum parkii* and is composed principally of triglycerides containing an oleic acid moiety at the 2-position and saturated fatty acids, usually stearic or palmitic acids, at the 1- and 3-positions.

(b) The ingredient meets the following specifications when tested using any appropriate validated methodology:

- (1) Saponification value of 185 to 195,
- (2) Iodine value of 28 to 43,
- (3) Unsaponifiable matter not to exceed 1.5 percent,
- (4) Free fatty acids not more than 0.1 percent as oleic acid,
- (5) Peroxide value not more than 10 milliequivalents/equivalent (meq/eq),
- (6) Lead not more than 0.1 part per million (ppm),
- (7) Copper not more than 0.1 ppm.

(c) In accordance with § 184.1(b)(3), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity: Confections and frostings as defined in § 170.3(n)(9) of this chapter, coatings of soft candy as defined in § 170.3(n)(38) of this chapter, and sweet sauces and toppings as defined in § 170.3(n)(43) of this chapter.

[63 FR 28895, May 27, 1998]

§ 184.1721 Sodium acetate.

(a) Sodium acetate ($C_2H_3O_2Na$, CAS Reg. No. 127-09-3 or $C_2H_3O_2Na \cdot 3H_2O$, CAS Reg. No. 6131-90-4) is the sodium salt of acetic acid and occurs naturally in plant and animal tissues. Sodium acetate may occur in either the anhydrous or trihydrated form. It is produced synthetically by the neutralization of acetic acid with sodium carbonate or by treating calcium acetate with sodium sulfate and sodium bicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 272, 273 which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in

§ 170.3(o)(12) of this chapter; and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.007 percent for breakfast cereals as defined in § 170.3(n)(4) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 0.6 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter and snack foods as defined in § 170.3(n)(37) of this chapter; 0.15 percent for hard candy as defined in § 170.3(n)(25) of this chapter; 0.12 percent for jams and jellies as defined in § 170.3(n)(28) of this chapter and meat products as defined in § 170.3(n)(29) of this chapter; 0.2 percent for soft candy as defined in § 170.3(n)(38) of this chapter; 0.05 percent for soups and soup mixes as defined in § 170.3(n)(40) of this chapter and sweet sauces as defined in § 170.3(n)(43) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27815, June 25, 1982]

§ 184.1724 Sodium alginate.

(a) Sodium alginate (CAS Reg. No. 9005-38-3) is the sodium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Sodium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 274, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations: